

Section 11. Exposure Reporting and Management

Exposure Reporting Responsibilities

The ultimate responsibility for reporting exposures, spills, and other biological hazards rests with the Principle Investigators, supervisors, and the RML employees. Such exposures and hazards need to be reported to supervisors, principal investigators, the Biosafety Officer and the Occupational Safety and Health Manager immediately upon becoming aware of the situation.

It is strongly suggested that employees notify their personal physician or appropriate healthcare worker of their place of employment and the agent with which they work. In addition, all personnel are to report immediately to their supervisor, the RML Biosafety Officer or the RML Occupational Safety and Health Manager any signs or symptoms of disease that might be a result of exposure to agents with which they work.

The material contained in this section is based on the comprehensive Biological Exposure Control Plan that RML has developed. Although there is considerable redundancy, for completeness, the current draft of that RML Biological Exposure Control Plan is provided as Appendix 11 of the IRF Emergency Response Plan.

Post-Exposure Evaluation and Follow-up

In the event an employee sustains a potential exposure to an infectious agent, the Biosafety Officer will notify the RML Infectious Disease Adviser, and they will make the initial evaluation of an exposure, including whether to notify the RML Associate Director or to convene the RML BEAP (see below). If deemed necessary, post-exposure evaluation and follow-up will be provided by Marcus Daly Community Hospital or the Regional Referral Hospital (RRH) for RML employees.

The Biosafety Officer and the Infectious Disease Advisor will be following the care provided to assure appropriate care is given. The Infectious Disease Advisor will serve as medical consultant or attending physician in emergency management, short-term care, and follow up of any laboratory acquired infection as needed and requested by the Biosafety Officer or Associate Director for RML. In addition, any occupational exposure to an infectious agent must be reported to the RML Occupational Safety and Health Manager (OSHM). The RML OSHM will complete US Department of Labor Form CA-2, "Notice of Occupational Disease and Claim for Compensation".

If required, employee counseling is provided free of charge through the Employee Assistance Program (AEP) administered by Federal Occupational Health. Their 24-hour hotline number is 1-800-222-0364. If you contact them, please indicate that you work for RML and that you are part of NIH.

Emergency care will be provided to visitors and contract personnel who sustain a potential exposure. These individuals will be referred to their private or company physicians for follow-up.

In the event of an incident that poses a potential risk of exposure to exotic agents present in the IRF, NIH/RML will provide contractors, special volunteers and visitors with the specialized emergency healthcare required to respond to a potential exposure to such agents. These individuals would also be considered by the Biological Exposure Assessment Program (BEAP, see “Exposure Management” below) in any incident that occurred.

Post-Exposure Incident Review

In the event an employee sustains a potential exposure to an infectious agent including HIV or other bloodborne pathogens, the Biosafety Officer as well as the employee’s supervisor will review the incident. In certain cases, the review will involve members of the RML BEAP (see below). The RML Biological Incident Investigation Form (Appendix 10) will be utilized.

As part of the incident review, a sharps injury log will be maintained for the recording of percutaneous injuries and mucous membrane exposures. The log contains information on the type and brand of device involved in the incident; the department and work area where the incident occurred; and an explanation of how the incident occurred. The log will be maintained by the Occupational Safety and Health Manager and used to gather information that may aid in the implementation of safer technologies. The information in the sharps injury log shall be recorded and maintained in such manner as to protect the confidentiality of the injured employee.

All work-related needlestick injuries and cuts from sharp objects that are contaminated with another person’s blood or other potential infectious material (as defined by 29 CFR 1910.1030) will be entered in the OSHA 300 Log as an injury using the OSHA 301 Injury and Illness Incident Report. All required records are kept for a minimum of five (5) years following the end of the calendar year that the records cover.

Exposure Management

RML Biological Exposure Assessment Program (RML BEAP)

In order to deal with the possibility that an incident, exposure or illness involving a work-related infectious agent might occur, the **Rocky Mountain Laboratories Biological Exposure Assessment Program (RML BEAP)** has been established. The RML Biological Exposure Assessment Program provides for local (RML) and institutional (NIAID/NIH) assessment of incidents, exposures and illnesses related to intramural use of biological agents, as well as on evaluation, therapy, recommendations, and corrective actions. The overriding concern of the program is to provide rapid and appropriate medical evaluation, treatment and prophylaxis for any exposed individual.

Although the RML BEAP functions semi-autonomously, ultimate responsibility and authority for these matters is vested with the Division of Occupational Health and Safety (DOHS), Office of Research Services (ORS), National Institutes of Health (NIH).

Membership of the RML BEAP

The following individuals are the members of the RML BEAP assigned to the RML campus:

- The Associate Director for RML
- The RML Senior Administrator or equivalent (position pending)
- The RML Biosafety Officer
- The RML Occupational Safety and Health Manager
- The RML Infectious Disease Adviser
- The relevant Principal Investigator(s) or supervisor(s)
- The relevant RML Laboratory Chief(s)
- The Chairperson of the RML Institutional Biosafety Committee

The following individuals are the members of the RML BEAP assigned to the Bethesda NIH campus:

- The Director of the NIAID Division of Intramural Research (NIAID DIR)
- A representative of the NIH Division of Occupational Health and Safety (NIH DOHS)

The following individuals will be notified and/or added to the RML BEAP as needed on an ad hoc basis:

- The Responsible Official for the RML Select Agent Program
- The Chief of the Rocky Mountain Veterinary Branch
- The leader of the RML Hazmat Team
- The RML Radiation Safety Officer
- The Ravalli County Health Officer
- Ravalli County Public Health Nursing Department
- The RML Communications and Public Liaison Officer

Operations of the RML BEAP

The Exposure Response Plan and the specific SOPs dictate the obligations for RML workers to report biological incidents, potential exposures and/or possible work related infectious diseases. These incidents may become evident in several ways:

- Obvious release of or exposure to infectious materials or infected animals. For this purpose, a release is considered to be any loss of material outside of the primary containment.
- Recognition of a possible work-related illness in the absence of any obvious signs of exposure as judged by an RML worker, contract employee, RML visitor, or his/her health care provider. (NOTE: The State of Montana requires all Montana health care providers to report patients diagnosed, or suspected, with any reportable disease to their county health departments.)
- Failure of biocontainment or failure to execute proper biosafety practices and procedures.

- Identification of a possible work-related reportable disease by the Ravalli County Public Health Nursing Department

The primary goal of this program is to provide the best possible medical care to any staff member who sustains an exposure to a biological agent. **Therefore, the first priority is to complete emergency first aid treatment and immediate clean up procedures.** Any detailed or specific information for evaluation, treatment, follow-up and surveillance is contained in the SOPs for particular infectious agents.

Notifications and Procedures

- It is the responsibility of each staff member and individual to report any such incident, as soon as is practical, to the laboratory supervisor and the RML Biosafety Officer.
- The Biosafety Officer will notify the RML Infectious Disease Adviser, and they will make the initial evaluation of an exposure.
 - The RML Biological Incident Investigation Form (Appendix 10) will be utilized.
 - A limited number of other individuals are also authorized to contact the Infectious Disease Adviser. In the event that the Infectious Disease Adviser is contacted, he/she will notify the RML Biosafety Officer.
 - The RML Infectious Disease Adviser will advise the RML Biosafety Officer on the need for any immediate evaluation, treatment, prophylaxis, or vaccination.
 - The RML Infectious Disease Adviser will advise the RML Biosafety Officer on the need to involve the Regional Referral Hospital (RRH) or the local ambulance service.
- Any occupational exposure to an infectious agent must also be reported to the RML Occupational Safety and Health Manager (OSHM). The RML OSHM will complete US Department of Labor Form CA-2, "Notice of Occupational Disease and Claim for Compensation" (<http://www.dol.gov/esa/regs/compliance/owcp/ca-2.pdf>).
- In the event that the incident involves a potential exposure or illness resulting from a BSL-3 or BSL-4 agent, the RML Biosafety Officer and the RML Infectious Disease Adviser will notify the Associate Director. The Associate Director will immediately notify the NIAID DIR and the NIH DOHS, and convene a meeting of the RML BEAP.
- In the event that the incident involves potential exposure or illness resulting from a BSL-2 agent, the RML Biosafety Officer and the RML Infectious Disease Adviser will notify the Associate Director. They will make a recommendation as to whether or not to convene a meeting of the RML BEAP.
- The Associate Director for RML is a Core Member of the Ravalli County Health Emergency Advisory Team (HEAT) (see below). In the event that the HEAT is activated for a public health issue that might be referable to RML, the Associate Director will convene a meeting of the RML BEAP.

- The RML BEAP will assess the incident and the exposure level, and will evaluate measures already taken or proposed to deal with the incident.
- In rare and exceptional circumstances, the NIH DOHS may elect to assume control of managing the exposure.
- The RML BEAP will assess any immediate threat or risk to laboratory operations, employees, facilities, the public and the environment, and will identify measures necessary to address, abate, or mitigate any residual or ongoing threat or risk. This will include determining the level of decontamination or any interruption of operations that might be required.
- In the event that it is determined that an incident poses a public health hazard, the Ravalli County Health Officer and the Ravalli County Public Health Nursing Department will be notified. The specific management of perceived or actual public health hazards is the province of the Ravalli County Public Health Nursing Department and the Ravalli County Health Emergency Advisory Team (HEAT). The role, membership, and methods for convening the HEAT are contained in Tab 5.50 of the Ravalli County Emergency Operations Guidelines. In brief, the HEAT team is the first group convened in the event of an actual or perceived public health emergency and will advise local emergency responders in their response to an incident. The Associate Director for RML is a Core Member of the HEAT.

RML/NIH will cooperate as much as possible with state and local officials in responding to any incident arising at the IRF that the BEAP determines poses a public health hazard. Assistance will be provided whether the incident arises from possible exposure of a staff member at RML, a contractor, or a visitor. Both state and local officials have authority over public health matters, and RML/NIH does not intend to usurp these agency's authorities. While the NIH is restricted under Federal law from agreeing to pay expenses in advance or providing any full indemnification to affected individuals and is limited by the Privacy Act in the amount of person medical information that it can provide, RML/NIH will provide full technical assistance to state and local officials in responding to any such incidents and in ensuring that the public health and the health of any potentially affected individuals are protected. While no local or state health agency has indicated that it will seek reimbursement from the NIH for expenses that might result from responding to public health incidents arising from potential exposures of individuals at the RML, the NIH will explore possible mechanisms for reimbursing state and local agencies for any such expenses that arise.

- Notifications will be based on the RML Incident Notification System. A comprehensive description of notifications is detailed in Appendix 6
 - In the event of any potential exposure in BSL-3 or BSL-4 areas or release of BSL-3 or BSL-4 agents, the Associate Director will notify the Ravalli County Public Health Officer and the head of the Ravalli County Public Health Nursing Department. The County Health Officer and the RML Infectious Disease Adviser will determine the need to notify the public and local or state governmental officials.
 - The Responsible Official for the RML Select Agent Program must notify the Select Agent representative at the CDC in the event of any Select Agent release or exposure, and also complete and submit a "Report of

Theft, Loss or Release of Select Agents and Toxins” form (APHIS/CDC Form 3).

- The RML BEAP, in conjunction with the NIAID/NIH Office of Communication and Public Liaison, will prepare, approve, and release any news statements.
- The RML BEAP will determine the need to collect and quarantine any samples of potentially infectious materials involved in the incident, or to stop laboratory operations in the affected area.
- In the event the incident is related to work with experimental animals, the RML BEAP will determine the need to collect and quarantine any live animals, animal sera, secretions or tissue samples for future analysis.
- The RML BEAP will continue to meet as necessary to monitor the incident, investigate the cause of the incident, and evaluate additional recommendations and other measures needed to resolve the incident, provide for all appropriate internal and outside notifications (Appendix 6), and implement remedial or corrective actions.
- The RML Biosafety Officer will work with the relevant staff to develop a corrective plan to prevent future incidents.
- The RML Infectious Disease Adviser will advise the RML BEAP if observation of close contacts, family members or others is warranted.
- If necessary, the RML BEAP will advise the Associate Director to convene the RML Crisis Management Team.

Meetings of the RML BEAP

- The RML BEAP will meet on an *as needed* basis as outlined above.
- Meetings will be convened by the Associate Director at the direction of the RML Biosafety Officer.
- The Associate Director, or in his absence the RML senior administrator or equivalent, will chair RML BEAP meetings. In exceptional circumstances, the NIH DOHS may chair the meetings.
- The RML Biosafety Officer serves as the Executive Secretary, and maintains all records, correspondence, and RML BEAP meeting notes.
- The RML Biosafety Officer, with the assistance of other members as needed, will be responsible for preparing a post-exposure incident review on each incident. This report, at a minimum, will contain a description of the incident, all measures taken to deal with the incident, and all recommendations implemented to prevent a recurrence. The RML BEAP will review and approve this report. The review will be forwarded to the proper officials and authorities.
- In the event that the incident involves a Select Agent, the Responsible Official for the RML Select Agent Program must complete and submit a “Report of Theft, Loss or Release of Select Agents and Toxins” form (APHIS/CDC Form 3) to the proper authorities.

- The RML Biosafety Officer will provide a summary of any incident to the RML Institutional Biosafety Committee at the next scheduled meeting.

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